

All of claims 8-12 and 17-20 positively recite steps of manipulation with a narrower scope than that of independent claim 1. For example, claim 8 positively recites a step of delivering RF energy from an RF energy source. This step further limits the scope of independent claim 1 that recites the step of "delivering a sufficient amount of energy through the skin surface.....". It is understood by one of ordinary skill in the art that this step clearly requires delivery of RF energy, not any other type of energy, thus significantly limiting the scope of the method claim. Similar reasoning is applied to claim 17 which positively recites a step of delivery microwave energy, not any other type of energy, to tighten the loose skin surface.

Applicants submit that claims 8-12 and 17-20 further narrow the scope of independent claim 1 and are sufficient definite under 35 U.S.C. §112, Second Paragraph. Withdrawal of this ground of rejection is respectfully requested.

II. Rejections under 35 U.S.C. §103

The Examiner rejects claims 1, 2, 8, 9, 17—27, 69 and 70 under 35 U.S.C. §103 (a) as being unpatentable over Sand (US Patent No: 4,976,709) in combination with Storm III (US Patent No: 4,140,130). The Examiner also rejects claim 8-12 under 35 U.S.C. §103 (a) as being unpatentable over Sand in combination with Storm III and further in view of Lax et al. (US Patent No: 5,569,242).

Independent claim 1 as specifies a method for treating a loose skin. According to the method, the energy delivery surface of an energy source (e.g., an RF electrode) is positioned on the surface of the loose skin and in conjunction with the creation of reverse thermal gradient on the skin sufficient energy is delivered to tighten the loose skin.

In contrast, Sand teaches a method for reshaping cornea by directly irradiating the cornea using laser. See "Summary of the Invention", column 4, line 23-31. There is neither teaching nor suggestion of the claimed steps of positioning the energy delivery surface of an energy source in conjunction with the creation of reverse thermal gradient so as to treat the loose skin.

The secondary reference, Storm III, fails to supply these requisite elements missing in Sand. Storm III teaches a method of treating tumors by using hyperthermia, which is completely irrelevant to the claimed method of treating a loose skin by delivering energy in conjunction with the creation of reverse thermal gradient to modify collagen matrix in the skin and subcutaneous soft tissue in order to achieve esthetic effects. To the contrary, Storm III

teaches specifically heating the tumor-bearing or deep musculo-skeletal tissue while "maintaining the skin and subcutaneous tissue therebeneath in a suitably relatively cooled state". Column 2, lines 39-43. Thus, Storm III not only fails to suggest the claimed method but also effectively teaches away from the present invention.

It is a well-established tenet of patent law that when an obviousness rejection is based upon the teachings of a combination of references, there must be something in the art as a whole to suggest the desirability of making the combination. Grain Processing v. American Maize 5 USPQ2d 1788, 1792 (Fed. Cir. 1988). As the Federal Circuit has cautioned on several occasions, when prior art references are based upon a selective combination of elements from more than one reference, there must be some reason for the combination other than the hindsight gleaned from the claimed invention itself. Interconnect Planning Corp. v. Feil 774 F2d 1132, 1143 (Fed. Cir. 1985).

Applicants respectfully submit that the Examiner impermissibly has based the present rejection upon hindsight. There is nothing in the cited references which would suggest the claimed method for treating a loose skin. The disclosure of laser sight correction in Sand does not provide a suggestion that a sufficient amount of energy should be delivered in conjunction with the creation of reverse thermal gradient to tighten loose skin. Since the Examiner has failed to show any motivation to provide the method as claimed, the Examiner has failed to set forth a *prima facie* case for obviousness under 35 U.S.C. §103 (a). Withdrawal of this ground of rejection is respectfully requested.

CONCLUSION

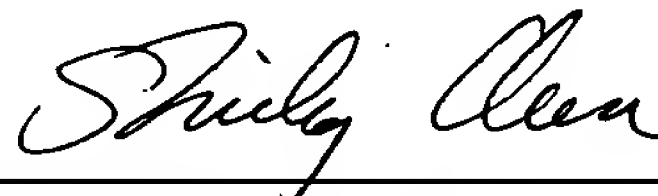
In light of the arguments set forth above, Applicants earnestly believe that they are entitled to a letters patent, and respectfully solicit the Examiner to expedite prosecution of this patent application to issuance. Should the Examiner have any questions, the Examiner is encouraged to telephone the undersigned.

The Commissioner is authorized to charge any fees which may be required, including petition fees and extension of time fees for a small entity, to Deposit Account No. 23-2415 (Docket No. 16904-727).

Respectfully submitted,

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PENDING CLAIMS

A method of treating a loose skin surface overlying a collagen containing tissue site, comprising:

- identifying a person suspected of having the loose skin surface;
- providing an energy source with an energy delivery surface;
- positioning the energy delivery surface on the loose skin surface;
- producing energy from the energy source;

creating a reverse thermal gradient, wherein a temperature of the skin surface is less than a temperature of the collagen containing tissue; and

delivering a sufficient amount of energy through the skin surface to contract at least a portion of the collagen containing tissue to tighten the loose skin surface.

2. The method of claim 1, wherein delivering energy includes delivering a sufficient amount of energy through the loose skin surface without creating a substantial cell necrosis in the loose skin surface.

8. The method of claim 1, wherein delivering energy includes delivering RF energy from the energy source that is an RF energy source.

9. The method of claim 8, wherein positioning the energy delivery surface includes positioning an energy delivery surface of an RF electrode on the loose skin surface.

10. The method of claim 9, further comprising: applying electrolytic media to the loose skin surface from a source of electrolytic media coupled to the RF electrode.

11. The method of claim 10, wherein applying electrolytic media includes applying an electrolytic solution to the loose skin surface.

12. The method of claim 10, wherein applying electrolytic media includes applying an electrolytic gel to the loose skin surface.

17. The method of claim 1, wherein delivery energy includes delivering a sufficient amount of microwave energy to tighten the loose skin surface.
18. The method of claim 1, wherein delivery energy includes delivering a sufficient amount of ultrasound energy to tighten the loose skin surface.
19. The method of claim 1, wherein delivering energy includes delivering a sufficient amount of energy through the skin surface to partially denature the collagen containing tissue by cleaving heat labile cross-links of collagen molecules.
20. The method of claim 1, wherein creating a reverse thermal gradient includes providing a cooling medium to cool the loose skin surface.
21. The method of claim 1, wherein treating a loose skin surface overlying a collagen containing tissue site includes contracting a portion of the collagen containing tissue site that is in a subdermal layer.
22. The method of claim 1, wherein treating a loose skin surface overlying a collagen containing tissue site includes contracting a portion of the collagen containing tissue site that is in a deep dermal layer.
23. The method of claim 1, wherein treating a loose skin surface overlying a collagen containing tissue site includes contracting a portion of the collagen containing tissue site that is in a subcutaneous dermal layer.
24. The method of claim 1, wherein treating a loose skin surface overlying a collagen containing tissue site includes contracting a portion of the collagen containing tissue site that is facial and muscle tissue.

25. The method of claim 1, wherein delivery energy includes delivering sufficient amount of energy such that the average temperature of the collagen containing tissue does not exceed 80 degrees C.

26. The method of claim 1, wherein delivery energy includes delivering sufficient amount of energy such that the average temperature of the collagen containing tissue does not exceed 75 degrees C.

27. The method of claim 1, wherein delivery energy includes delivering sufficient amount of energy such that the average temperature of the collagen containing tissue does not exceed 70 degrees C.

69. The method of claim 1, further comprising:
detecting a temperature of the skin surface.

70. The method of claim 69, wherein delivering energy to the collagen containing tissue site includes delivering a sufficient amount of energy to the tissue site in response to the detected temperature of the skin surface to tighten the loose skin surface.